Remarks

Claims 1-35 and 46-48 are pending in the application. Claims 36-45 and 49-73 have been canceled. Claims 1-35 and 46-48 have been rejected. Claims 1-12, 14, 19-20, 22-35 and 46-48 have been amended. No new matter has been added. Importantly, the claim amendments should not be construed to be an acquiescence to any of the claim rejections. Rather, the amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicants expressly reserve the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

Election/Restriction

The Applicants affirm the election to prosecute the invention of Group I, claims 1-35 and 46-48, drawn to a method, computer product and system for use in the analysis of gene or protein expression information.

Response to rejections based on 35 USC § 101

Claims 1-35 and 46-48 are rejected because the Examiner contends that the claimed invention is directed to non-statutory subject matter. Specifically, the Examiner explains that "simply determining variability of expression levels provides no useful information; since there is no further indication (*i.e.* steps) [as to] what the variability of expression levels represents." In light of these comments, the Applicants amend independent claims 1, 46 and 48 to include the step of using the measures of variability "in the analysis of gene or protein expression information". The Applicants respectfully suggest that the amended claims comply with 35 USC § 101 and therefore request the withdrawal of these rejections.

Response to rejections based on 35 USC § 112¶1

Claims 1-35 and 46-48 are rejected as failing to comply with the enablement requirement. Specifically the Examiner contends that "one skilled in the art would not understand what the information means and what to do with the information after the generation of the determined 'variability of the expression levels' without an intended

goal." As mentioned above, independent claims 1, 46 and 48 have been amended to include the step of using the measures of variability "in the analysis of gene or protein expression information". Thus, a "goal" is clearly expressed in the amended claims. Accordingly, the Applicants respectfully request the withdrawal of the rejection of claims 1-35 and 36-48 based on 35 USC § 112¶1.

Response to rejections based on 35 USC § 112¶2

Claims 1-35 and 46-48 are rejected as being indefinite.

In the first instance, the claims are rejected for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. The Examiner believes the claims are indefinite for "failing to recite a final process step, which agrees back to the preamble." Again, as mentioned above, independent claims 1, 46 and 48 have been amended to include the step of using the measures of variability "in the analysis of gene or protein expression information". These claims now possess a process step which agrees back to the preamble.

In addition, the Examiner rejects as vague and indefinite, claim 1 and all claims dependent therefrom for their use of the limitations "G genes", "S samples" and "C classes". In order to expedite the prosecution of this application the Applicant has removed from the rejected claims all instances of "G genes", "S samples" and "C classes", replacing them with "a number of" genes, samples or classes.

Additional rejections based on alleged vagueness and indefiniteness were advanced against the claim set for the limitation "classes representing cellular states". On page 8 of the specification, lines 16 and 17, the term "cellular state" is explained to be synonymous with "biological state" and "physiological state". One skilled in the art would understand that the state of a biological sample can be measured by the content, activities or structures of its cellular constituents. The state of a biological sample, as used herein, is taken from the state of a collection of cellular constituents, which are sufficient to characterize the cell or organism for an intended purpose. In one embodiment, the cellular or biological state of a cell can vary between an optimal (e.g., asymptomatic) level and one of complete non-function (*i.e.* etiology). Given the above

explanation, the Applicants respectfully submit that they have established that "cellular state" is not a vague and indefinite term.

Claim 22 was additionally rejected for using the word "similar" without clarification as to the range of values possible. The Applicants have amended said claim to adhere to proper claim construction. The Applicants have replaced the word "similar" with the allowed term "substantially identical", thereby narrowing the claim scope. 35 USC § 154(d)2.

Claims 31, 32 and all claims dependent therefrom are additionally rejected as being vague and indefinite for using the term "significantly". In order to expedite prosecution, the claims have been amended to remove the term "significantly".

Claim 33 is additionally rejected for reciting "C-1 dimensions" which is considered by the Examiner to be confusing. In order to expedite the prosecution of the application, claim 33 has been amended to remove the rejected wording.

Lastly, claim 35 is further rejected for its use of the language "F score", which is considered by the Examiner to be vague and indefinite. The Examiner requests clarification as to "where a definition or criteria for such language" can be found in the Specification. The Applicant directs the Examiner's attention to pages 74-75 of the specification, starting at the bottom of page 74, where a explanation of "F score" can be found. In addition, claim 35 has been amended to include further clarification regarding the calculation of an F score.

Therefore, based on the amendments and explanations presented above, the Applicants respectfully request the withdrawal of all rejections based on 35 USC § 112¶2.

Response to rejections based on 35 USC § 102(a)

Claims 1-6, 9-11 and 46-48 are rejected as being anticipated by Kerr *et al.* Because Kerr *et al.* does not separate samples into classes it does not teach all of the limitations of the rejected claims; therefore, it is not an anticipatory reference. Specifically, claims 1, 46 and 48 include the limitation that "said samples are classified

into a number of classes." Consequently, the Applicants respectfully request the withdrawal of all rejections based on 35 USC § 102(a).

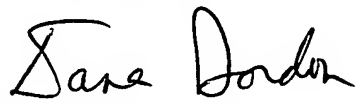
Fees

The Applicants believe there are no required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any required fee to our Deposit Account, **06-1448**.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

Respectfully submitted,
Patent Group
Foley Hoag LLP

By: 

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